In the claims:

1.(Amended) A method of treating [or preventing] obesity in a human subject comprising administering to said subject an effective amount of an amylin or an amylin agonist.

REMARKS

Applicants have carefully considered the Examiner's September 16, 1998 Office Action, and provide the following remarks. Claims 1 through 6 are pending in the application.

35 USC § 112

The Examiner notes that, "Applicants have provided support in the instant specification and examples for a method of single 'treating' obesity in a human subject comprising administering an effective amount of an amylin or an amylin agonist" (September 16, 1998 Office Action at page two). The Examiner, however, has rejected pending claims 1-6 under 35 U.S.C. § 112, first paragraph, on the assertion that the specification "while being enabling for a method of treating obesity in a human subject comprising administering an effective amount of an amylin or an amylin agonist, does not reasonably provide enablement for a method of 'preventing' obesity in a human subject" (September 16, 1998 Office Action at page two).

Although applicants disagree with this conclusion, solely in order to expedite the prosecution of this application, applicants

have amended independent claim 1 to confirm that the method is directed to "treating" obesity. This amendment is without prejudice to the inclusion of another claim or claims in a continuing application, and the amendment to independent claim 1 may not be construed as limiting in any way the rights of exclusion to which applicants will be entitled to under 35 U.S.C. § 271 upon the issuance of a patent, including all rights under the Doctrine of Equivalents. Having amended the claims to recite a method of treating obesity in a human subject in accordance with the suggestion of the Examiner at page two of the September 16, 1998 Office Action, applicants request that this rejection be reconsidered and withdrawn.

35 USC § 102(e)

The Examiner rejected claims 1-3 under 35 U.S.C. § 102(e) as allegedly anticipated by Rink *et al.*, U.S. Patent No. 5,739,106, issued on April 14, 1998, for "Appetite Regulating Compositions" on application filed June 7, 1995. The Examiner states that this § 102 rejection was entered because Rink *et al.* teaches "methods for controlling body weight, reducing food intake and suppressing appetite in mammals including humans using an amylin agonist" (September 16, 1998 Office Action at page three). In support, the Examiner cites the abstract and column 11, lines 25 and 26.

Applicants request that this rejection be reconsidered and withdrawn. Notwithstanding whether § 102(e) may be applied

against applicants' invention, Rink *et al.* does not describe the methods of treating obesity claimed by applicants herein. Rink *et al.* is directed to (1) a composition that includes an amylin agonist admixed with a cholecystokinin ("CCK") agonist or (2) a composition that includes a hybrid peptide that incorporates features of amylin agonist peptides and CCK agonist peptides. Thus, Rink *et al.* does not teach the use of an amylin agonist alone for controlling appetite, let alone for treating obesity in human subjects, and the anticipation rejection cannot stand.

Anticipation requires that all the limitations of the rejected claim be found in a single prior art reference; e.g., C.R. Bard, Inc. v. M3 Systems, Inc., 48 U.S.P.O. 2d 1225, 1239 (Fed. Cir. 1998) ("Anticipation requires that the identical invention was already known to others, that is, that the invention is not new.") Rink *et al.* does not provide such a disclosure. The Examiner states that claim 85 of Rink *et al.* is drawn to a method for control of body weight in a mammal comprising administering a therapeutically effective amount of an amylin agonist such as $^{25, 28, 29}$pro-h-amylin, and that claims 83 and 84 are drawn to methods for suppressing food intake and for control of appetite in a mammal comprising administering a therapeutically effective amount of an amylin agonist such as $^{25, 28, 29}$pro-h-amylin. It is noted, however, that none of claims 83-85 refer to the administration of an amylin agonist.

Each of claims 83-85 refers to the administration of a composition of "any of claims 1-6, 17, 18, 32, 33, 46, 47, 61, 63 or 72." Claims 1-6, 17, 18, 32, 33, 46, 47, 61, 63 or 72 are all directed to compositions that comprise an amylin agonist and a CCK agonist admixed together (claims 1-6), to hybrid peptides comprising covalently linked amylin agonist and CCK agonist peptides (claims 17, 18, 32, 33, 46, 47, and 61), or to other specific hybrid peptides (claims 63 and 72). None of these claims describe the administration of an amylin agonist for treating obesity, and applicants request that the rejection be reconsidered and withdrawn.

35 USC § 103

The Examiner has also rejected Claims 4-6 under 35 U.S.C. § 103(a) as allegedly unpatentable over Rink *et al.* as applied to claim 1 above, and further in view of Gaeta *et al.* (U.S. Patent No. 5,686,411, issued November 11, 1997 for "Amylin Agonist Peptides and Uses Therefor"). The Examiner acknowledged initially that, "Rink *et al.* do not teach the specific doses, times and route of administration recited in Claims 4-6." The Gaeta *et al.* patent, however, does not supply what Rink *et al.* lacks. Gaeta *et al.* is directed to various amylin agonist peptides, including $^{25, 28, 29}$pro-h-amylin, useful in the treatment of diabetes. Gaeta *et al.* does not contain any discussion of

obesity or the treatment of obesity. Thus, the Examiner's reliance on Gaeta *et al.* as teaching various doses of amylin agonist compounds for the treatment of obesity is misplaced.

The Examiner also rejected Claims 1-6 under 35 U.S.C. § 103(a) as allegedly unpatentable over Kolterman *et al.* (I) or Kolterman *et al.* (II) or Moyses *et al.* or Thompson *et al.* in view of Cooper *et al.* and Rink *et al.* In general, these additional articles relate to methods of treating patients with diabetes mellitus by administration of amylin agonists, in particular $^{25, 28, 29}$pro-h-amylin, which has been the subject of numerous clinical trials over the last several years, and is now in final phase 3 clinical testing by Amylin Pharmaceuticals. The Examiner acknowledges, in fact, that "Kolterman *et al.* [I] or Kolterman et al [II] or Moyses *et al.* do not teach a method of treating or preventing obesity by administering pramlintide to a human subject."

Additionally, while the Examiner states that, "Cooper *et al.* teach that 'obesity which frequently accompanies' type II or non-insulin dependent diabetes mellitus (NIDDM) is a result of rather than a risk factor for, NIDDM (abstract)," this does not support the Examiner's rejection. In fact, it was Dr. Cooper, co-founder of Amylin Pharmaceuticals and the discoverer of the amylin molecule, who subsequently invented and patented methods for

treating obesity using amylin antagonists (U.S. Patent Nos. 5,364,841 and 5,280,014 issued to Cooper and Greene (the other co-founder of Amylin Pharmaceuticals) on January 18 and November 15, 1994, respectively, for "Treatment of Obesity and Essential Hypertension and Related Disorders"). As described and claimed in the Cooper and Greene '841 and '014 patents, the treatment of obesity is by the administration of antagonists and blockers of amylin, and is not by the use of amylin or amylin agonists as described in the instant application. Thus, these patents teach away from the subject matter claimed herein. Also teaching away from the obesity treatment described and claimed in the instant application is U.S. Patent No. 5,656,590, issued on August 12, 1997, to Rink *et al.* for "Treatment of Anexoria and Related States." That patent describes and claims methods for the treatment of patients suffering from anexoria or a similar condition by administering an amylin or an analog thereof in order to increase weight.

Thus, it will be seen that, in contrast to the Examiner's conclusion that it would have been obvious to use an amylin agonist to treat obesity, the art taught the opposite. Amylin Pharmaceuticals, which for the last decade has been the world leader in the investigation and development of amylin and amylin agonist molecules for the treatment of human disorders, had itself determined that it was amylin antagonists rather than

amylin agonists that would find utility in the treatment of obesity and that, in fact, the use of amylin agonists would lead to weight gain rather than weight decrease. See the '841 and '014 patents. Applicants respectfully request that this § 103 rejection also be reconsidered and withdrawn.

CONCLUSION

Applicants submit that the pending claims are in condition for allowance, and seek an early notice thereof. Should the Examiner have any remaining questions he is encouraged to telephone the undersigned so that they may be promptly resolved.

Respectfully submitted,

Dated: 16 Mar 99

By: _____

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